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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,822	11/01/2001	Alberto L. Mendoza	MSU 4.1-542	6022

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EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/998,822	Applicant(s) MENDOZA, ALBERTO L.	
	Examiner N. M. Minnifield	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
4a) Of the above claim(s) 1-3 and 13-32 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 4-12 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☒ Claim(s) 1-3 and 13-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed November 10, 2003 is acknowledged and has been entered. Claim 4 has been amended. Claims 4-12 are now pending in the present application. All rejections have been withdrawn in view of Applicant's amendment and/or comments with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. This application contains claims 1-3 and 13-32 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. Claims 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mendoza et al (1992, J. Clinical Microbiology, 30/11:2980-2983) taken with Mendoza et al (1992, Micropathologia, 119:89-95).

The claims are directed to a method for treatment of pythiosis or prophylaxis against pythiosis in a mammal comprising providing a vaccine (intracellular cytoplasmic antigens and extracellular cytoplasmic antigens of *Pythium insidiosum*) and cytoplasmic antigens, which included the 28, 30 and 32 kDa antigens vaccinating the mammal with the vaccine. The claims also recite the method of preparation of the vaccine.

Mendoza et al (J. Clinical Microbiology) teaches vaccines prepared from various antigens (proteins) derived from *Pythium insidiosum* (ATCC 58643) and that the organism was grown in Sabouraud broth (materials and methods, p. 2980). The prior art also teaches the methods of filtration, solubilization, sonication and centrifugation (p. 2981, left hand column). The prior art teaches the inactivation of the proteins using thimerosal/merthiolate (p. 2981). The art teaches that "... the supernatant was collected and used to provide antigens." (p. 2981). The art further teaches filtration by PM-10 membranes, which removes less than 10,000 molecular weight components. The second supernatant obtained after sonication contained soluble antigens and/or intracellular proteins. Mendoza et al teaches the investigation of antigens from *P. insidiosum*, which may be important in the immune response of horses (i.e. mammals) to *P. insidiosum* infection (p. 2980, right hand column). The prior teaches the claimed invention except for the use of extracellular proteins.

However, Mendoza et al (Micropathologia) teaches the evaluation and production of two vaccines, cell-mass vaccine and soluble concentrated antigen (intracellular proteins), both of which have been derived from cells of *Pythium insidiosum* (ATCC 58643) and the organism was grown in Sabouraud broth (abstract; materials and methods). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the two supernatants (supernatants containing intracellular cytoplasmic and extracellular proteins) of the two prior art references with a reasonable expectation of success of obtaining a vaccine for the treatment of infection caused by *Pythium insidiosum*. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the vaccines since both references teach the

importance of preparing a vaccine for the treatment of infections caused by *Pythium insidiosum*; both the extracellular and intracellular cytoplasmic proteins have been found to be useful as vaccines to treat infection caused by *Pythium insidiosum*. Both vaccines of the prior art provide protection and cured the horses. The two vaccines of the prior art function in the same manner as the method of treating pythiosis or prophylaxis against pythiosis in a mammal comprising administering the same vaccine composition as claimed by Applicant. It would have been obvious to a person of ordinary skill in the art to combine both these vaccines into one vaccine for the purpose of providing better cure rates and protection to the animals. It is prima facie obvious to combine two compounds each of which is taught by the prior art references to be useful for the same purpose, the idea of combining them flows logically from their having been individually taught in the prior art. The claimed invention is prima facie obvious in view of the prior art absent any convincing evidence to the contrary.

This rejection is maintained for the reasons of record. Applicant's arguments filed November 10, 2003 have been fully considered but they are not persuasive. The Mendoza Declaration under 37 CFR 1.132 filed November 10, 2003 is insufficient to overcome the rejection of claims 4-12 based upon a 103 unobviousness rejection as set forth in the last Office action.

Applicant has asserted that the rejections is using Applicant's disclosure in the application with his earlier references to link them together and that one skilled in the art would not have thought to combine the Mendoza et al references, and certainly the results achieved could not have been predicted. However, it is prima facie obvious to combine two compositions each of which is taught by the prior art

(Mendoza et al, 1992, J. Clinical Microbiology, 30/11:2980-2983 taken with Mendoza et al, 1992, Micropathologia, 119:89-95) to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. Therefore, claims that require no more than the mixing together of two conventional items or components sets forth prima facie obvious subject matter. In re Kerkhoven, CCPA, 205 PQ 1069.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (i.e. using Applicant's disclosure in the application), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With regard to the Mendoza 1.132 declaration, declarant states that certain references (cited in the declaration at page 2) show that the claimed vaccine is unexpectedly much more effective than his earlier vaccines described in the 1992 Mendoza et al references cited in the Office Action. Declarant also states that he could not have predicted the results with the vaccines of the claims, and it was not at all obvious to him that such results could be achieved. However, it is noted that the claims do not recite any limitation with regard to the degree of effectiveness or better results over prior vaccines prepared by Mendoza et al. Further, it is well settled that a patent cannot be granted for an applicant's discovery of a result, even

though it may be unexpectedly good, which would flow logically from the teaching of the prior art. The claimed invention is prima facie obvious in view of the prior art absent any convincing evidence to the contrary.

5. No claims are allowed.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

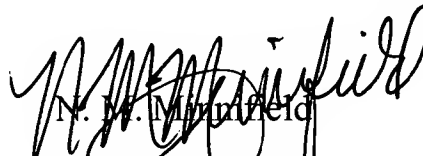
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



N. M. Minfield
Primary Examiner

Art Unit 1645

NMM

February 13, 2004